REMARKS

In the subject Office Action dated January 4, 2006, claims 1-20 were examined. In response thereto, claims 1, 3, 7, 8, 13 and 17 are amended, claims 2, 12 and 14 are cancelled, claim 21 is added, and claims 4-6, 9-11, 15, 16, and 18-20 remain under active prosecution. Applicants assert that the amendments are subject in the originally filed application and do not introduce new subject matter.

In the subject Office action, claims 1, 5, 6, 13 and 15 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent 6,171,321 (Gifford et al.). Claims 1-4, 13 and 14 were rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent 6,485,496 (Suyker et al.). Claims 7, 11, 18 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gifford in view of U.S. 6,451,029 (Yeatman), and claim 17 as being unpatentable over Suyker in view of Gifford and further in view of Yeatman. Claims 8, 9, 10 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Suyker in view of U.S. Patent 5,855,312 (Toledano).

Turning to independent claim 1, the claim as amended to incorporate the features of dependent claim 2 recites in part proximal and distal leaves that cantilever toward a central portion actuate an anastomotic device from a cylinder shape to a hollow rivet shape.

In the subject Office action, the Examiner relied upon Suyker to disclose these features. Applicants assert however, that the mere fact that a wedge (42) with a cavity (46) is used to crimp together the ends of pin-like elements (20), or staples, does not suggest an elongate cannula operably configured to separately transfer the proximally and distally directed longitudinal motions respectively to the distal and proximal portions of the surgical instrument with the actuating member. Moreover, Applicants note Suyker's use of wedges to rock or pivot the staple elements into piercing contact with the vessel walls. Consequently, Suyker fails to anticipate the additional features of claim 2 and claim 2 should be allowed for at least these additional reasons. Moreover, insofar as Suyker fails to suggest the separately transferred motions by an elongate cannula, or even proximally and distally directed longitudinal motion produced by the handle, there is no suggestion or motivation to modify the distal end surface (41), and the 90° tilting wedges (46) of Suyker, (which are controlled independently by the housing (40) and a control element (44)), to be operably configured (with one element, a cannula), to separately transfer the two longitudinal motions. Therefore,

reconsideration and allowance of claim 1 is respectfully requested, as well as for claims 3-11 that depend therefrom.

With particular reference to claims 3 and 4 that depends from claim 1, the claims recite the further features of a first tube and second tube slidingly received in the first, connected to proximal and distal portions of the actuating member, and a third tube between the other two engaged to the center portion of the actuating member. In the subject Office action, the specific structures and procedural steps relied upon by the Examiner were not consistently, and sometimes specifically, pointed out in Suyker. To the extent understood by Applicants, the Examiner is either equating the distal end surface (41) and/or the blunt end part (38) with the claimed actuating member of the present invention. However, Applicants assert that none of these three possibilities anticipates the elements of these claims. Suyker simply does not teach a surgical instrument wherein an elongate cannula comprises a first tube *connected to the proximal portion of the actuating member*. The actuating member of the present invention (sometimes referred to in the Office action as element 41 of Suyker, and sometimes as 38 (and even as element 14)) is not taught or disclosed in this reference. Further, there is no second tube received in a first tube connected to the distal portion of the actuating member, nor a third tube interposed between the first and second tubes (see Fig 28 and Col. 7, lines 7-32), nor any connection to a central portion of the actuating member. There is no "central portion" of an actuating member in Suyker. By contrast, the distal end surface and the blunt end part work simply as plungers, detainers, or guides to "move bars with beveled points in a forward direction to axially direct wedges which deflect the aforementioned pin-shaped staple elements into tissue walls." (Col. 7, lines 21-32). Consequently, Suyker fails to anticipate the claims and thus reconsideration and allowance is respectfully requested.

With particular reference to claim 5 that depends from claim 1, the claim recites the further feature of a "piercing tip distally coupled to the actuating member". In the subject Office Action, the Examiner relied upon Gifford to disclose "a tapered tip (which may include a distal piercing surface) distal to the molded actuation member to assist in forming an anastomotic opening through apposite tissue walls of two gastrointestinal passages." Applicants assert however, that the mere fact that a cutter anvil (136) is used in conjunction with a ***tubular*** vessel punch cutter (137) that telescopically slides on the distal end of a vessel punch (much like a cookie cutter cuts dough) does not suggest a piercing tip distally coupled

to an actuating member. Moreover, Applicants note that Gifford requires a separate vessel punch mechanism that fits inside the inner tube of the stapling mechanism (as discussed above) to operate the telescoping tubular cutter slidably operable in conjunction with the anvil, with no coupling to an actuation member. Consequently, Gifford fails to anticipate the additional feature of claim 5 and claim 5 should be allowed for at least this additional reason. Moreover, insofar as Gifford fails to suggest an actuation member formed of proximal and distal leaves distally coupled to a piercing tip, there is no suggestion or motivation to modify the inner drive member (132) and cutter anvil (136) to be distally coupled together. Reconsideration and allowance of claim 5 is respectfully requested.

With particular reference to claim 6 that depends from claim 1, the claim recites the further feature of a piercing tip comprising an enterotomy creation tip. In the subject Office Action, the Examiner recites a definition of "enterotmoy" (sic) from Merriam-Webster, as an "incision into the intestines" and asserts that the anvil (136) of Gifford is capable of creating an incision in the intestines. However, that assertion ignores the clear and consistent use of the role of the "piercing tip" of the present invention. The Examiner cannot look at the ordinary meaning of the term...in a vacuum. Rather [he] must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d. 1313 (Fed. Cir. 2005). The Examiner's interpretation of the anvil (136) of Gifford is inconsistent with the clear and consistent use of the term in the specification of the present invention, and is contrary to how a person of ordinary skill in the art would interpret the claim term within the context of the claim, the entire patent and the prosecution history.

It appears from the Office Action that the Examiner relied primarily upon the figures in rejecting claim 6 as anticipated by Gifford. Applicants assert that Gifford teaches nothing regarding element 136 (the cutter anvil) being a tool for "incision in the intestines" or being distally coupled to the actuating member. Gifford instead teaches a "tubular cutter that slides over the cutter anvil until the inner lumen of the tubular cutter creates a *shearing action* to create a cut hole through the vessel walls" (Col. 17, lines 44-51). In essence, the only coupling, which is not distal coupling, may creatively be considered between the inner drive member and the cutter (137) – but not with the anvil (136). As such, Gifford fails to disclose the features that would anticipate the claimed invention of claim 6. Reconsideration and allowance of claim 6, is respectfully requested for at least these additional reasons.

With particular reference to claim 13 that depends from claim 1, the claim recites an additional feature of a surgical instrument comprising a cannula; and actuating member distally and laterally presented on the cannula for receiving a generally cylindrical anastomosis ring; and a first control operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring. In the subject Office Action, no additional structure of Gifford was pointed out by the Examiner as corresponding to the claimed cannula and actuating member distally and laterally presented for receiving a generally cylindrical anastomosis ring. Gifford completely lacks any disclosure or suggestion of the cited additional limitation and the Examiner struggled so much at trying to force it, that the item previously identified as *"a compressive actuating force" (see page 2, paragraph 3, line 5)* is now suddenly an "*actuating member*" (see page 3, line 4). Regardless of this, neither of these two separately distinct items disclose, address, or teach the present limitations. Therefore, Applicants assert that a prima facie case for anticipation has not been made. Further, neither the plunger (142) nor any aspect of Gifford's stapling device includes a control (hydraulics, electronics, pneumatics or computer, or robotic) for operatively compressing a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring (see paragraph [0052] of the present published application). Consequently, reconsideration and allowance of claim 13 is requested for at least these additional reasons.

Turning to claim 16, the claim recites a surgical instrument further comprising an enterotomy creation tip distally coupled to the cannula. Again, the Examiner has not pointed to any structure of Gifford as corresponding to the claimed enterotomy creation tip distally coupled to the cannula. Because the Gifford patent does not teach every element of the present invention, a rejection under 35 U.S.C. § 102(b) is no longer proper.

Turning to independent claim 13, applicants note that the claim recites the same limitations described above with regard to claim 1. Applicants further note that the Claims 12 and 13 include additional limitations that are not taught or suggested in the art of record, thus forming independent basis for novelty and non-obviousness. Consequently, reconsideration and allowance is respectfully requested for claims 12 and 13, as well as for claims 14-20 that depend therefrom.

Regarding the 103(a) rejection of claims 7, 11, 18 and 19, Applicants respectfully traverse the rejection because a prima facie case of obviousness has not been, and cannot be, established. To establish a *prima facie* case of obviousness, as specified in MPEP § 2143, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. Applicants further note that all words in a claim must be considered in judging the patentability of that claim against the prior art, and an obviousness rejection permits no exception to this rule. (MPEP § 2143.03).

The cited references either singularly or in combination fail to disclose an anastomosis applier that facilitates implantation through a single bodily tissue lumen with an actuating member comprised of distal and proximal leaves that are pivotally moveable between an unactuated cylindrical position to a hollow rivet forming position for implanting an anastomotic ring device. Moreover, the cited references fail to appreciate the problem of the single lumen access and do not provide a means for applying an anastomotic ring device without the use or insertion of anvils and staples. Consequently, there is no suggestion or teaching to modify the instrument of Gifford or the other cited references to address this problem. Therefore, the cited references either singularly or in combination fail to render the claim unpatentable. For these additional reasons, claims 7, 11, 18 and 19 should be allowed.

With respect to Claim 7, the Examiner concedes that Gifford is silent regarding "the instrument comprising a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen, and the tip comprising a veress needle" and the Examiner suggests that Yeatman will fill this void. As discussed above, the entire relevant focus of Gifford "involves vascular staples where an anchor member forms an attachment with a target vessel wall and a coupling member forms an attachment with a bypass graft vessel, with the coupling member inserted (with the tissue attached) into the anchor member" (see Gifford column 6, lines 24-33). There is no teaching, suggestion, or motivation in Gifford to provide a pneumatic conduit or a veress needle.

Page after page of teaching by Gifford focuses on the use of anvils and laparoscopic insertions, along with a complicated two-piece stapling mechanism which performs the

anastomosis procedure by passing the end of a graft vessel through an inner lumen until the end of the vessel extends a short distance from the distal end of the sleeve, where the end of the graft vessel is then everted over the inner flange of the fitting to form an attachment for suture or spikes to hold the graft vessel in place. An inner flange and the everted end of the graft vessel are then passed through an opening that has previously been made where, finally, an outer flange is slid over the graft vessel from the free end (see column 7, lines 11-17). There is no suggestion or teaching regarding an integrated surgical tool that incorporates a tapered tip with a distal piercing surface in the form of a veress needle that avoids inadvertent damage to tissue, does not use staples or anvils, uses existing trocar ports with a minimum of suturing, and inflates the lumens. At column 17, lines 42-53, Gifford is actually teaching away from Applicant's invention. There, Gifford is teaching an invention that utilizes a separate punch mechanism, where a tubular cutter (137) slides over an anvil (136) to create a hole, not a piercing surface pressed against the tissue walls with a ball that spingedly withdraws into the veress needle to expose the piercing surfaces where the tissue is displaced by the extended ball and not a knife tip, as in the amended claimed invention. Moreover, one skilled in the art, reading Gifford in view of Yeatman, would not arrive at the combination of the surgical tool as currently claimed in amended claim 7. The shortcomings of Gifford are discussed above, and Gifford, quite simply, is the truest essence of non-analogous art. Yeatman's stapling device simply does not make up for the deficiencies of Gifford, nor is it a means for performing anastomosis. Combining Gifford with Yeatman does not result in Applicant's claimed invention, and therefore, per 35 U.S.C. § 103, one skilled in the art would not expect success. For these several reasons, the rejection should be removed and Claim 7 should be allowed. Additionally, Claims 11, 18 and 19 which now also depend from an allowable claim, should also be allowed.

With respect to Claims 8, 9, 10 and 20, Applicants submit that a *prima facie* case of obviousness cannot be established based on the cited art due to the fact that Suyker and Toledano, either alone or in combination, do not teach or suggest these limitations. Applicants note, with traverse, the suggestion in the Office Action that Toledano teaches a "electrical illumination source and control" by teaching an optical fiber buncle (sic) (mislabeled as 71 instead of 70). (Office Action at page 7, last line). Applicants respectfully submit that this disclosure of Toledano does not constitute a teaching of a "electrical illumination source and control" as one of ordinary skill in the art would understand the term

"electrical illumination source and control." Nevertheless, even accepting the Examiner's purported finding of a "electrical illumination source and control" in Toledano as correct merely for the sake of argument, Applicants note that the purported "electrical illumination source and control" of Toledano is not a battery power source and control switch incorporated into the handle with twisted wire pair conductors passing through the internal tube to the tapered tip with proximally directed electroluminescence material for deployment illumination (see paragraph [0049] of the current published application). Toledano is focused on internal imaging where the bundle of optical fibers work in conjunction with an objective lens assembly to project an image of the inner wall of the intestines into the near end of the fiber bundle (70) (see column 9, lines 8-17). Applicants further note that Suyker gives no assistance to Toledano in making up for this deficiency. In light of the foregoing, Claims , 9, 10 and 20 are patentable over the combination of Suyker and Toledano, and therefore Applicants respectfully request that the rejections be withdrawn.

Applicants note that a new claim 21 has been added that includes the features described above for claim 1 as amended to further include an astomotic ring installed thereon.

To the extent that Applicants have not explicitly addressed certain aspects of the present rejections, please do not construe the same as an admission as to the merits of the rejections. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicants traverse the rejections and preserve all rights and arguments, including rights with respect to arguments not explicitly raised herein.

Conclusion

In light of the remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. If there are any additional matters which may be resolved by telephone or fax, Applicants encourage the Examiner to contact their representative, David E. Franklin at (513) 651-6856 or dfranklin@fbtlaw.com to expedite issuance of this application.

Because the application was filed with 3 independent claims and 20 claims total, and now, after amendment, contains 3 independent claims and 18 claims total, no new claim fees are due. A check in the amount of $120 is enclosed for a one month's extension. The Commissioner for Patents, however, is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

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